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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/500,115	02/08/00	PONIKAU J	07039-104002

HM22/0710

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EXAMINER	
BAWA, R	

ART UNIT	PAPER NUMBER
1619	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/500,115	Applicant(s) Ponikau
	Examiner Mr. Raj Bawa	Art Unit 1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4-25-01 and 6-11-01*

2a)☐ This action is **FINAL.** 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-129, 131-133, 135-137, and 139-141* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideratio

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-129, 131-133, 135-137, and 139-141* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some* c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)

16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *11, 13*

18)☐ Interview Summary (PTO-413) Paper No(s). _____

19)☐ Notice of Informal Patent Application (PTO-152)

20)☐ Other:

Detailed Action

(1) The amendment dated June 6, 2001 has been entered.

(2) The outstanding rejection under 35 U.S.C. 112(2) has been withdrawn in view of the applicant's remarks.

(3) The "Information Disclosure Statements" submitted on 4-25-01 and 6-11-01 have been recorded. In view of these, the finality of the office action dated 4/6/01 has been withdraw. Below appears a new office action:

(4) Claims 127-129, 131-133, 135-137, and 139-141 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite "...non-invasive fungus-induced rhinosinusitis comprising the presence of allergic mucus (or polyp, eosinophilia)..." This phrase is vague and confusing in the context recited because is unclear whether the presence of the said materials (allergic mucus, polyp or eosinophilia) is a symptom of the rhinosinusitis or are contributed by the host. If applicants' intention is the former, following phrase may be considered: "...non-invasive fungus-induced rhinosinusitis wherein the rhinosinusitis is accompanied by the presence of allergic mucus (or polyp, eosinophilia)..."

It is the Examiner's position that the above phrase does not meet the threshold requirement of clarity and precision and is not in compliance for definiteness of 35 U.S.C. 112, second paragraph. Definiteness of the claims is important to allow others who wish to enter the

marketplace to ascertain the boundaries of protection that are provided by the claims (*Ex parte Kristensen* 10 USPQ2d 1701, 1703).

(5) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 70-129, 131-133, 135-137 and 139-141 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cody et al. (AL, IDS June 11, 2001), in view of Bent III et al. (AE, IDS June 11, 2001).

Cody et al. teach general methods for treatment of AFS. These methods include nasal administration of antifungal agents or steroids (See, treatment on page 1078 and table V on page 1079).

Bent III et al. has been relied to establish (I) that allergic fungal sinusitis inherently includes the presence of polyps and allergic mucus; and (ii) the usefulness of topical steroids for AFS (See, abstract; page 260, last paragraph bridging to page 261).

Cody et al. do not specifically teach the particular regimen or the particular administration time and duration. However, optimization of such result-effecting parameters are considered within the skill and scope of ordinary artisan, absent evidence to the contrary. In fact, a person of ordinary skill in the art would have been motivated to employ well-known antifungal agents, including azole or macrolide compounds, optionally in combination with steroid, for the

treatment of AFS. The employment of a composition which is known to be useful in the treatment of a particular disorder (such as allergic fungal sinusitis) is considered clearly obvious for prevention of the same disorder, since therapeutic effects would have been reasonably expected. The employment of the second ingredient, which is known to be useful for the same purpose is seen to be obvious. It is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; the motivation to combine them flows logically from their having been individually taught by the prior art. Hence, the claimed invention which is a combination of two known germicides sets forth prima facie obvious subject matter. See, *In re Kerkhoven*, 205 USPQ 1069. The employment of antifungal compounds herein, in an article of manufacture or composition useful for topical treatment of allergic fungus sinusitis is motivated by the prior art since topical irrigation with antifungal agents in known in the treatment of allergic fungus sinusitis. Finally, the method of making a composition by mixing or combining ingredients is clearly nominal and considered prima facie obvious.

Note that: (I) the cited art is analogous because it pertains to the field of the inventor's endeavor and is also reasonably pertinent to the particular problem with which the inventor is involved. *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992); (ii) a comprising-type language does not exclude other steps, elements or materials. *Cues Inc. vs. Polymer Industries*, USPQ2d 1847 (DC ND GA 1988); (iii) it is well established that the claims are given the broadest interpretation during examination; (iv) a conclusion of obviousness under 35 U.S.C.

103(a) does not require absolute predictability, only a reasonable expectation of success; and (v) references are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures. *In re Bozek*, 163 U.S.P.Q. 545 (CCPA 1969).

In light of the foregoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the claims would have been obvious within the meaning of 35 U.S.C. 103(a).

(6) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mr. Raj Bawa whose telephone number is (703)-308-2423. The examiner can normally be reached on Tuesday through Friday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash, can be reached on (703)-308-2328. The fax phone number for the organization where this application or proceeding is assigned is (703)-305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)-308-1235.

RB

RAJ BAWA, Ph.D.
PRIMARY EXAMINER